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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,853

05/27/2005

Pascal Aznar

103.001

4377

41754

7590

12/17/2009

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EXAMINER

MARTINEZ, BRITTANY M

ART UNIT

PAPER NUMBER

1793

MAIL DATE

DELIVERY MODE

12/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,853	Applicant(s) AZNAR, PASCAL	
	Examiner BRITTANY M. MARTINEZ	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☒ Claim(s) 1 and 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/29/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

Applicant's arguments/remarks and amendments filed on September 9, 2009, have been carefully considered. **Claims 1-6** are pending in this application, with **Claims 1 and 2** amended. **Claims 1-6** have been examined.

Claim Objections

1. **Claims 1 and 2** are objected to because of the following informalities: an "a" should be placed before "particle size" in **Claims 1 and 2**; and it is suggested that "pores" be changed to "a pore size" in **Claims 1 and 2**. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 4 and 5** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. It is unclear what is meant by "similar forms."

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office action.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 2 and 6** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams (US 5,559,039).

3. With regard to **Claims 1 and 2**, Williams discloses a column for liquid chromatography comprising spherical and porous silica gel having a particle size of 4.5 micrometers and a pore size of 60 angstroms (Williams, "Abstract;" c. 7, l. 22-39; c. 8, l. 46-48; "Example 1"). With regard to **Claim 2**, while Williams does not explicitly disclose semi-spherical silica gel, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Williams.

4. With regard to **Claim 6**, Williams discloses adapting the column to purify synthetic products in quantities of 50 mg (Williams, "Example 9").

5. **Claims 1, 2 and 6** are also obvious over Williams because anticipation is the epitome of obviousness.

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6. **Claims 1-6** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Koh (*Journal of Chromatography A*).

7. With regard to **Claims 1 and 2**, Koh discloses a column for preparative liquid chromatography comprising spherical and porous silica gel having a particle size of 6 micrometers and a pore size of 60 angstroms (Koh, "Abstract;" p. 225, "Table 1"). Koh further discloses a column for preparative liquid chromatography comprising spherical and porous silica gel having a particle size of 12 micrometers and a pore size of 90 angstroms (Koh, "Abstract;" p. 225, "Table 1"). With regard to **Claim 2**, while Koh does not explicitly disclose semi-spherical silica gel, Koh discloses "nearly spherical" silica gel (Koh, p. 237, "Conclusion"). In any event, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Koh.

8. With regard to **Claim 3**, Koh discloses the column containing around 240 g of porous spherical or semi-spherical silica gel (Koh, p. 225; p. 232, "Table 3").

9. With regard to **Claims 4 and 5**, Koh discloses the column manufactured with tubes and pistons (Koh, p. 224, "Experimental").

10. With regard to **Claim 6**, Koh discloses adapting the column to purify synthetic products in quantities of 0.1 to 0.8 g (Koh, p. 224, "Experimental").

11. **Claims 1-6** are also obvious over Koh because anticipation is the epitome of obviousness.

12. **Claims 1, 2 and 4** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over SUPELCO (*Guide to Solid Phase Extraction*).

13. With regard to **Claims 1 and 2**, SUPELCO discloses a column for preparative liquid chromatography comprising spherical and porous silica gel having a particle size of 40 micrometers and a pore size of 60 angstroms (SUPELCO, p. 1-3, 5-8, 10 and 11). With regard to **Claim 2**, it is well-known in the art that “semi-spherical” refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of SUPELCO.

14. With regard to **Claim 4**, SUPELCO discloses the column manufactured with tubes and syringe bodies (SUPELCO, p. 1-3, 5-8, 10 and 11).

15. **Claims 1, 2 and 4** are also obvious over SUPELCO because anticipation is the epitome of obviousness.

16. **Claims 1 and 2** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schwartz (US 5,128,114).

17. With regard to **Claims 1 and 2**, Schwartz discloses a column for chromatography comprising spherical and porous silica gel having a particle size of 5-20 micrometers and a pore size of 2-20 nanometers (Schwartz, “Abstract,” c. 1, l. 12-18 and 53-56; c. 3, l. 9-12 and 45-49; c. 5, l. 29-33; c. 8, l. 62-64; c. 9, l. 47-51). With regard to **Claim 2**, it is well-known in the art that “semi-spherical” refers to something that has a somewhat

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spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Schwartz.

18. **Claims 1 and 2** are also obvious over Schwartz because anticipation is the epitome of obviousness.

19. **Claims 1, 2 and 4** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kanda et al. (US 6,360,589 B1).

20. With regard to **Claims 1 and 2**, Kanda discloses a column for preparative liquid chromatography comprising spherical and porous silica gel having a particle size of 3-50 micrometers and a pore size of 60-80 angstroms (Kanda, "Abstract;" Figures 1-4; c. 1, l. 5-10; c. 11, l. 16-35; c. 14, l. 9-11). With regard to **Claim 2**, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Kanda.

21. With regard to **Claim 4**, Kanda discloses the column manufactured with tubes and syringe bodies (Kanda, "Abstract;" Figures 1-4; c. 1, l. 5-10; c. 11, l. 16-35; c. 14, l. 9-11).

22. **Claims 1, 2 and 4** are also obvious over Kanda because anticipation is the epitome of obviousness.

23. **Claims 1, 2, 4 and 6** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Teraoka et al. (US 5,587,082).

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24. With regard to **Claims 1 and 2**, Teraoka discloses a column for preparative chromatography comprising spherical and porous silica gel having a particle size of 37 micrometers and a pore size of 15 nanometers (Teraoka, "Abstract;" Figure 1; Examples). With regard to **Claim 2**, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Teraoka.

25. With regard to **Claim 4**, Teraoka discloses the column manufactured with tubes and syringe bodies (Teraoka, "Abstract;" Figure 1).

26. With regard to **Claim 6**, Teraoka discloses adapting the column to purify synthetic products in quantities of 1.6 g (Teraoka, "Abstract;" Figure 1; Examples).

27. **Claims 1, 2, 4 and 6** are also obvious over Teraoka because anticipation is the epitome of obviousness.

28. **Claims 1 and 2** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matsushita et al. (US 4,341,634).

29. With regard to **Claims 1 and 2**, Matsushita discloses a column for chromatography comprising spherical and porous silica gel having a particle size of 4-40 micrometers and a pore size of 80-100 angstroms (Matsushita, "Abstract;" c. 2, l. 41-50). With regard to **Claim 2**, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Matsushita.

30. **Claims 1 and 2** are also obvious over Matsushita because anticipation is the epitome of obviousness.

Claim Rejections - 35 USC § 103

31. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 5,559,039) as applied to **Claims 1 and 2** above, and further as discussed below.

32. Williams does not disclose the column containing between 10 mg and 1 kg of spherical and porous silica gel or semi-spherical and porous silica gel (**Claim 3**).

33. With regard to **Claim 3**, an expected silica gel quantity is a result effective variable since one of ordinary skill in the art would expect different properties in the product as such amount varies. Since the silica gel quantity is a result effective variable, it is within the skill of one of ordinary skill in the art to develop a suitable silica gel quantity. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Further, choosing a silica gel quantity would be a matter of product design and routine optimization, and thus, would have been obvious to one of ordinary skill in the art at the time of invention.

34. **Claims 3 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Teraoka et al. (US 5,587,082) as applied to **Claims 1 and 2** above, and further as discussed below.

35. With regard to **Claim 5**, Teraoka discloses the column manufactured with tubes and syringe bodies (Teraoka, "Abstract;" Figure 1).

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36. Teraoka does not disclose the column containing between 10 mg and 1 kg of spherical and porous silica gel or semi-spherical and porous silica gel (**Claim 3**).

37. With regard to **Claim 3**, an expected silica gel quantity is a result effective variable since one of ordinary skill in the art would expect different properties in the product as such amount varies. Since the silica gel quantity is a result effective variable, it is within the skill of one of ordinary skill in the art to develop a suitable silica gel quantity. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Further, choosing a silica gel quantity would be a matter of product design and routine optimization, and thus, would have been obvious to one of ordinary skill in the art at the time of invention.

38. **Claims 4 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 5,559,039) as applied to **Claims 1 and 2** above, and further in view of Fuji (XP-002198180).

39. Williams does not disclose the column manufactured with tubes as well as syringes or similar forms (**Claims 4 and 5**).

40. With regard to **Claims 4 and 5**, it is well-known in the art that columns for flash chromatography are manufactured with tubes and syringe bodies, as evidenced by Fuji (Fuji, p. 1, "Flash chromatography system").

41. Thus, it would have been obvious to one of ordinary skill in the art to try to modify the column disclosed by Williams with the column components taught by Fuji because one of ordinary skill in the art could have pursued the known potential flash

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chromatography column options within his or her technical grasp with a reasonable expectation of success.

42. **Claims 1 and 2** are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (*Journal of Bacteriology*) in view of Kamegawa et al. (*Journal of Colloid and Interface Science*).

43. With regard to **Claims 1 and 2**, Watanabe discloses a column for chromatography comprising 200/350 mesh spherical silica gel (Watanabe, p. 2293). The difference between the silica gel of Watanabe and that of the instant application is Watanabe does not explicitly disclose the silica gel having pores with a size between 30 and 300 angstroms. However, the silica gel disclosed by Watanabe (Fuji-Davidson's microbead silica gel 4B, 200/350 mesh) has an average pore size of 7.7 nm, as evidenced by Kamegawa (Kamegawa, p. 94, "Materials"). With regard to **Claim 2**, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Watanabe.

44. **Claims 1 and 2** are rejected under 35 U.S.C. 103(a) as being unpatentable over Danishefsky et al. (US 2002/0058817 A1) in view of Sigma-Aldrich ("Silica gel").

45. With regard to **Claims 1 and 2**, Danishefsky discloses a column for flash chromatography comprising silica gel with a particle size between 40 and 63 micrometers (Danishefsky, 0394). The difference between the silica gel of Danishefsky

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and that of the instant application is Danishefsky does not explicitly disclose the silica gel being spherical or having pores with a size between 30 and 300 angstroms.

However, the silica gel disclosed by Danishefsky is spherical and has an average pore size of 80 angstroms, as evidenced by Sigma-Aldrich (Sigma-Aldrich, "Silica gel"). With regard to **Claim 2**, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Danishefsky.

46. **Claims 1 and 2** are rejected under 35 U.S.C. 103(a) as being unpatentable over Still et al. (*J. Org. Chem.*) in view of Sigma-Aldrich ("Silica gel").

47. With regard to **Claims 1 and 2**, Still discloses a column for flash chromatography comprising silica gel with a particle size between 40 and 63 micrometers (Still, p. 2923-2924). The difference between the silica gel of Still and that of the instant application is Still does not explicitly disclose the silica gel being spherical or having pores with a size between 30 and 300 angstroms. However, the silica gel disclosed by Still is spherical and has an average pore size of 80 angstroms, as evidenced by Sigma-Aldrich (Sigma-Aldrich, "Silica gel"). With regard to **Claim 2**, it is well-known in the art that "semi-spherical" refers to something that has a somewhat spherical shape. Thus, a semi-spherical silica gel would be anticipated and obvious in view of the spherical silica gel of Still.

Prior Art

41. The following prior art made of record and not relied upon in this Office action is considered pertinent to Applicant's disclosure.

Document	Inventor/Author	Date	Citations
US 2002/0043462 A1	Ivory et al.	04/2002	Table 4; 0144
US 2003/0220330 A1	Yoshitaka et al.	11/2003	0121 and 0126-0127
US 2002/0058286 A1	Danishefsky et al.	05/2002	0345; 0456
US 2002/0128490 A1	Johnston et al.	09/2002	0090; 0097; 0101
US 7,109,377	Schreiber et al.	09/2006	c. 29, l. 54-62
US 4,743,377	Ohtsu et al.	05/1988	Abstract; c. 3, l. 15-33; Examples
US 4,830,921	Kitayama et al.	05/1989	Abstract; c. 2, l. 63-68; c. 3, l. 1-3; Examples
US 5,051,176	Miyano et al.	09/1991	Abstract; c. 2, l. 17-26; Examples
US 5,135,649	Kanda et al.	08/1992	Abstract; c. 3, l. 24-28; Examples
US 6,074,555	Boos et al.	06/2000	Abstract; Examples
"Effect of pore size..."	Kazue Tani et al.	1990	Entire Document

Response to Amendments

Applicant's amendments filed September 9, 2009, with respect to the Claims and Specification have been fully considered and are accepted.

Response to Arguments

48. Applicant's arguments filed September 9, 2009, with respect to the rejections over Ren, Ramage and Fuji (Applicant's Response, 9/9/09, p. 6-9) have been fully considered and are persuasive in view of the Declaration and exhibits submitted September 9, 2009. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made, as can be seen above.

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49. Applicant's arguments filed September 9, 2009, with regard to Williams and Schwartz (Applicant's Response, 9/9/09, p. 9) have been fully considered but they are not persuasive. As written, the instant claims do not require the column to be used in flash chromatography. Further, Williams discloses liquid chromatography generally.

50. It is highly recommended that Applicant review the documents listed under the "Prior Art" heading before considering Claim amendments. Several of the listed documents could be used to reject the pending claims based on varying interpretations of the instant claims, using the broadest reasonable interpretation

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRITTANY M. MARTINEZ whose telephone number is (571) 270-3586. The examiner can normally be reached on Monday-Friday 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached on (571) 272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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